

REMARKS

Initially, Applicants' attorney notes that the present Amendment has been prepared in accordance with the revised amendment format published in the Official Gazette Notice on February 25, 2003. More particularly, the revised amendment format is prepared in accordance with proposed revisions to 37 CFR 1.121. In such circumstances, Applicants' attorney respectfully requests waiver of the format requirements of 37 CFR 1.121.

By this Amendment, Applicants amend independent Claims 1 and 10 to clarify that the closely mating shrink fit between the bore of the screw and the driver is such that the driver may be removed from the bore. Claim 2 has been amended to substitute the word "bore" for the word "cannula".

The Examiner has rejected Claims 1-6 and 9 of the present Application under 35 U.S.C. § 102(b) as being anticipated by Mühling, et al. U.S. Patent No. 5,169,400. In particular, the Examiner asserts that the Mühling, et al. '400 patent teaches a bore exhibiting a close shrink-fit relative to the driver. Applicants respectfully traverse this assertion, as the Mühling, et al. '400 patent does not teach a close shrink-fit between the bore and the driver. One section of the Mühling, et al. '400 patent (col. 3, lines 25-50) teaches a friction-fit between a screwing-in tool and an insertion channel of a screw, but does not teach the formation of a shrink-fit between the screwing-in tool and the insertion channel. The other section of the Mühling, et al. '400 patent (col. 4, lines 32-40) actually discloses a melt-weld technique whereby a closure pin, used to seal the insertion channel within the screw, is rapidly turned within the insertion channel to "melt and weld the closure pin to the wall material" of the insertion channel, thereby "permanently fixing the closure pin in the insertion channel". In contrast, the driver of the present invention is closely mated with the bore of the screw through a shrink-fit, but is not permanently fixed to the wall of the bore and may, therefore, be removed from the bore (page 9, line 24 – page 10, line 4). Since the Mühling, et al. '400 patent does not teach a shrink-fit

between the bore of the screw and the driver such that the driver may be removed from the bore, Applicants urge that the amended Claim 1 is in condition for allowance, and that its dependent Claims 2-6 and 9 should also be allowed.

Claim 8 was rejected by the Examiner as being obvious under 35 U.S.C. § 103(a) over the Mühling, et al. '400 patent. Since, as discussed above, Claim 1, from which Claim 8 depends, is an allowable claim, Claim 8 is also an allowable claim.

The Examiner also rejected Claims 7 and 10-20 as being obvious under 35 U.S.C. § 103(a) over the Mühling, et al. '400 patent in view of Tunc U.S. Patent No. 5,827,287. Applicants respectfully note that there is no *prima facie* case of obviousness with respect to Claim 7 since the Mühling, et al. '400 patent does not teach the necessary feature of a shrink-fit between the bore of the screw and the driver such that the driver may be removed from the bore. Moreover, the Tunc '287 patent does not teach the addition of a bioabsorbable glass, bioabsorbable ceramic, biocompatible glass or biocompatible ceramic to the composition of the screw.

With respect to Claims 10-20, the Examiner flatly states that the steps recited in these claims would have obviously been carried out in the operation of the device of Claims 1-9. Applicants respectfully direct the Examiner's attention to independent Claim 10, which requires that the screw be heated and cooled in separate steps to create a closely mating shrink-fit between the bore of the screw and the driver such that the driver can be removed from the bore. Although the Mühling, et al. '400 patent addresses the removal of a screwing-in tool from an insertion channel, after it has been inserted therein (col. 3, lines 25-52), there is no teaching of heating or cooling steps between the insertion and removal of the screwing-in tool. The Mühling, et al. '400 patent teaches heating of the screw only in the context of fusing a closure pin with the wall of an insertion channel within a screw so that the closure pin is permanently fixed within the insertion channel. Therefore, the Mühling, et al. '400 patent clearly

teaches away from heating and cooling a polymeric screw so as to form a shrink-fit between a bore of a screw and a driver such that the driver may be removed from the bore. The Tunc '287 patent teaches the heating and cooling of a bioabsorbable screw in the context of modifying the screw's mechanical properties, but does not address the formation of a shrink-fit between any part of the screw and a removable piece.

For the reasons stated above, Applicants believe that the present application is in condition for allowance and respectfully urge the allowance of the claims presented therein. If the Examiner believes that there are additional issues to be addressed that may be resolved through a telephone interview, he is respectfully urged to contact Applicants' attorney at the telephone number provided below.

No fee is believed to be due in connection with the submission of this Amendment. If any such fees are due, including extension and petition fees, the Examiner is hereby authorized to charge them to Deposit Account No. 501402.

Respectfully Submitted,

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